

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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[Docket No. 78N-021A]

RIN 0910-AA01

Skin Protectant Drug Products for Over-the-Counter Human Use; Astringent Drug Products; Final Monograph; Direct Final Rule; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA) is confirming the effective date of October 27, 2003, for the final rule that appeared in the **Federal Register** of June 13, 2003 (68 FR 35290). The direct final rule amends the regulation that established conditions under which over-the-counter (OTC) skin protectant astringent drug products are generally recognized as safe and effective and not misbranded. This action revises some labeling for astringent drug products to be consistent with the final rule for OTC skin protectant drug products (68 FR 33362, June 4, 2003) and adds labeling for certain small packages (styptic pencils). This document confirms the effective date of the direct final rule. This action is part of FDA's ongoing review of OTC drug products.

DATES: Effective date confirmed: October 27, 2003.

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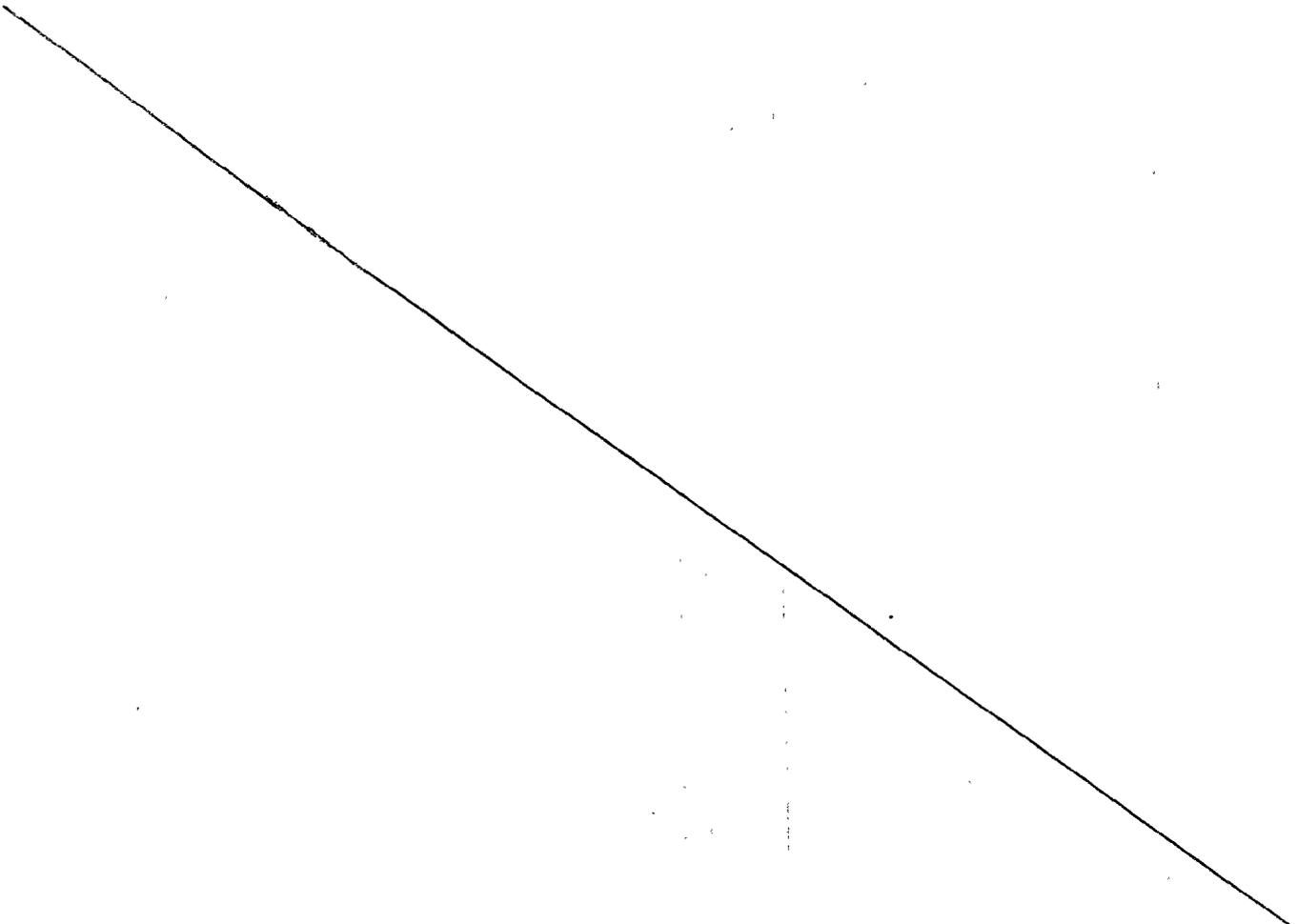
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FOR FURTHER INFORMATION CONTACT: Gerald M. Rachanow, Center for Drug Evaluation and Research (HFD-560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2307.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 13, 2003 (68 FR 35290), FDA solicited comments concerning the direct final rule for a 75-day period ending August 27, 2003. FDA stated that the effective date of the direct final rule would be on October 27, 2003, 60 days after the end of the comment period, unless any significant adverse comment was submitted to FDA during the comment period. FDA did not receive any significant adverse comments.

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

Accordingly, the amendments issued thereby are effective.



Dated: Oct 3, 2003
October 3, 2003.

cd03159

Jeffrey Shuren

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

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